K110143

JUN - 2 2011

510(k) SUMMARY
(Per 21 CFR 807.92)

General Company Information

Name: HET Systems, LLC
Contact: Howard Schrayer
Regulatory Affairs Consultant

Address: 1502 E 14th Street - Suite 2
Brooklyn, NY 11230

Telephone: (718) 645-6304
E-mail: hs.ss@verizon.net

Date Prepared April 15, 2011

General Device Information

Product Name: HET™ Bipolar Electrocautery Forceps

Classification: "Electrosurgical cutting and coagulation device and accessories"
Product code: GEI - Class II
21 CFR 878.4400

Predicate Devices

Valleylab, Inc. (now Covidien)
Valleylab Bipolar Forceps
510(k) K926414

Link Technology, Inc.
(subsequently Silverglide Surgical Technologies currently Stryker)
Bipolar Forceps
510(k) K992931
510(k) K093108 (Stryker)

Bissinger GmbH
Claris Non-Stick Bipolar Forceps
510(k) K051429

Predicate Devices (cont'd)

Curon Medical, Inc. (currently Mederi Therapeutics, Inc.)
RF electrosurgical generator and accessories
[510(k) K014216]

Description

The HET™ Electrocautery System is comprised of the HET™ Bipolar Electrocautery Forceps and the HET™ Monitor.

The HET™ Bipolar Forceps is a sterile, single-use bipolar forceps having a tapered tubular configuration. The device is connected via an integrated bipolar cabel to the bipolar output of an electrosurgical generator. The HET™ Bipolar Forceps has an integrated illumination and a temperature probe. The HET™ Bipolar Forceps can be connected and used with any commercial bi-polar RF generator which is rated less than 50W.

The HET™ Monitor is an optional accessory that can be used only with the HET™ Bipolar Forceps when used in conjunction with the CONMED HYFRECATOR® 2000 or the VALLEYLAB SURGISTAT II RF generators. The monitor displays the time (in seconds) of RF energy delivery and the temperature at the forceps-tissue interface. The HET™ Monitor does not generate RF energy.

Intended Use (Indications)

HET™ Bipolar Electrocautery Forceps is intended to be used for grasping, manipulating and coagulating soft tissue during general surgery.

The accessory monitor provides power for a timer, a temperature sensor and an LED light source mounted on the disposable forceps.

Substantial Equivalence

This submission supports the position that the HET™ Bipolar Electrocautery Forceps is substantially equivalent to a number of previously cleared devices, including the Stryker, Inc., Silverglide® electrocautery forceps.

The 510(k) Notice contains summaries of a study that was conducted to evaluate the in vivo performance of the device as compared to predicate devices. In addition, biocompatibility studies and electrical safety studies were conducted to demonstrate that the device was equivalent to predicate bipolar electrocautery forceps.

The forceps are provided sterile for single-patient-use.

Conclusions

HET Systems, LLC believes that the information provided establishes that similar legally marketed electrocautery forceps have been used for the same clinical application as the indications for the HET™ Electrocautery forceps. The material from which the HET Systems device is fabricated has an established history of use in medical applications; and devices produced by HET Systems have been tested in accordance with applicable guidelines and standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

HET Systems, LLC
c/o Howard Schrayer
1502 E 14th St., Suite 2
Brooklyn, NY 11230

JUN - 2 2011

Re: K110143
Trade/Device Name: HET Bipolar Electrocautery Forceps and Monitor
Regulation Number: 21 CFR 878.4400
Regulation Name: electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 15, 2011
Received: April 18, 2011

Dear Mr. Schrayer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K110143

Device Name: HET™ Bipolar Electrocautery Forceps

Indications For Use:

HET™ Bipolar Electrocautery Forceps is intended to be used for grasping, manipulating and coagulating soft tissue during general surgery.

The accessory monitor provides power for a timer, a temperature sensor and an LED light source mounted on the disposable forceps.

Prescription Use ___X_____ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110143